FDA Information Management and Office of Information Management

Strategic Plan *Version 1.1*

FY2012 - FY2016

September 2012

FOREWORD

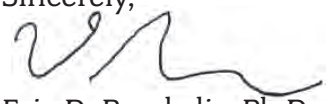
It is with great excitement that we bring you the first full version of the FDA Information Management (IM) Strategic Plan. During the time this document has been under development, we have reached out to many sources for feedback and are confident that each reader will feel the document was worth the wait.

In building this plan, careful attention was paid to both the Food and Drug Administration (FDA) Strategic Priorities and the Health and Human Services (HHS) Strategic Plan. We attempted to map and align each goal and objective within this document to each specific FDA objective, but in the end we decided that approach was unnecessary. In truth, each of the core goals of this plan [Infrastructure on Demand, Knowledge Architecture, Financial Opportunity, Office of Information Management (OIM) Workforce Transformation] is essential for the successful realization of every component of the FDA mission.

We also strove to keep this document clear for our customers and ourselves. While not always simple, the goals and objectives are simply stated and we are committed to their successful conclusion. It is our intent to publish annual updates and to use this plan as a living document that guides our efforts, without dictating them to the omission of the essential real-time feedback we will receive along our journey. We are also developing and utilizing more detailed internal documents that provide more specificity for our implementation processes.

Again, thank you for your support and enthusiasm.

Sincerely,



Eric D. Perakslis, Ph.D.
Chief Information Officer (CIO) and Chief Scientist for Informatics
Food and Drug Administration

FDA OIM VISION

FDA's technology and knowledge capability is modern, secure, accessible, cost-effective and exceeds customer and partner expectations.

FDA OIM MISSION

To provide the information, communication and knowledge infrastructure and services that enhance, transform and sustain the ability of the FDA to protect and promote the public health.

FDA OIM Guiding Principles

- Infrastructure that is Available on Demand
- Information as the Key Asset
- Excellence, Efficiency and Continuous Improvement
- Collaborations, Coalitions and Teamwork
- Interoperability and Enterprise Approach

FDA OIM VALUES

1. **Mission-First**
   We align all our activities with the goals and mission of FDA and we insist that all investments are judged by the value produced towards that mission

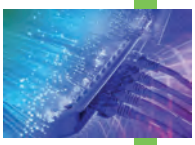
2. **Transparency and Accountability**
   We require the highest quality of integrity, ethical conduct, fiscal responsibility and openness in operations, processes and decision making

3. **Customer Service**
   We understand and embrace our responsibility to remove barriers to and enhance the productivity of the FDA workforce

4. **Innovation and Agility**
   We embrace the necessary rate of change within public health and medical and food product safety, and we will continuously evolve our processes and services

5. **Workforce Excellence**
   We are committed to the professional competence, continuous improvement, and the perpetual development of our most precious resource

GOALS



1. Provide Technology on Demand via the modernization of internal infrastructure and the provisioning of external capabilities that optimize the productivity of the FDA workforce

2. Develop the Knowledge Architecture and Infrastructure that enables smooth FDA operations, efficient review processes, risk-based analytics, and secure and seamless collaboration with public and private partners

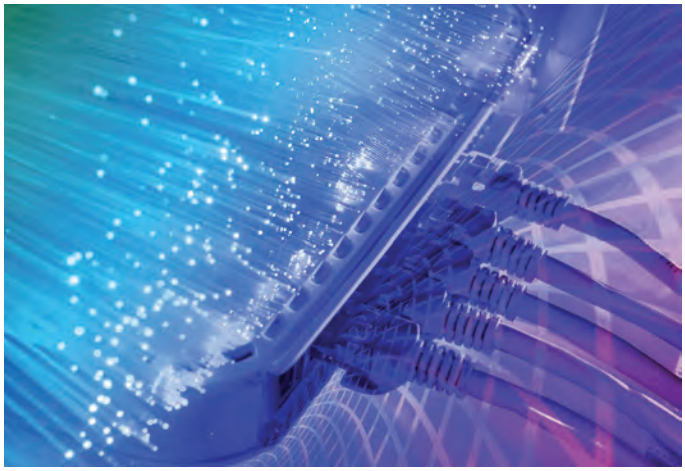
3. Create Fiscal Opportunity via the efficient delivery of high value services that reduce costs and create reinvestment opportunities

4. Develop a leadership pipeline of highly engaged, qualified and customer-centric employees that are experts in technologies and in the business and scientific domains which they serve

GOAL #1

Provide Technology on Demand via the modernization of internal infrastructure and the provisioning of external capabilities that optimize the productivity of the FDA workforce

DESCRIPTION



At the core, FDA is an information and process driven organization. The real-time connectivity and access to data and information is essential for daily operations as well as for the integrity of connectivity to the public that we serve and the many partners that work with and are dependent on FDA for the execution of their missions. This connectivity and access are dependent upon high quality, high availability and high performing data networks, server and application infrastructure, communication services, many simple and advanced computer applications, mobile workforce capabilities, and high quality, rapid and responsive service delivery.

This goal is intended to drive the modernization of the entire technology infrastructure at FDA as well as to enable the next generation of technologies, business capabilities, mobile services and collaborations that will enable FDA to meet its responsibilities to regulate a diverse, global product supply.

OBJECTIVES

1.1 Modernize Technology Infrastructure and Enable Cloud Computing by 2013

FDA IM provides an Agency-wide, 21st Century computing infrastructure that is secure, efficient, effective, scalable, flexible, and reliable; meets the FDA business requirements; and enhances FDA's operational capabilities via internal and external infrastructure.

1.2 Deploy an Agile, Net-Centric, Service-Based Technology Environment by 2014

The FDA systems environments must be flexible, reliable, expandable, predictable, resource conservative, maintainable, standards-based and cost effective.

1.3 Develop and deploy a comprehensive set of Workforce Mobility and Virtualization capabilities by 2014

Currently more than a third of the FDA workforce is not headquarters-based or works off-site. In addition, initiatives to streamline the physical footprint of government agencies have necessitated the development of specific strategies and services aimed at ensuring the productivity of an increasingly virtual workforce.

1.4 Provide business process and workflow management solutions by 2015

Business Process Management solutions (including workflow management technology and tracking of performance metrics) allow efficient use of human resources and optimize productivity. These tools also facilitate project management, maintenance of system inventories, and monitoring and optimization of system utilization and efficiency.

MAJOR ACTIVITIES and TIMING

		FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
1.A	Maintain a modern robust multi-tier enterprise computing infrastructure with virtualization	X	X	X	X	X
1.B	Maintain modern, high-speed redundant networks and telecommunications capability	X	X	X	X	X
1.C	Maintain consistency and reliability through standardized operational processes and change management	X	X	X	X	X
1.D	Provide efficient Information Technology (IT) equipment updating, property management, and disposition	X	X	X	X	X
1.E	Implement service-based architecture capabilities with use of common components			X	X	X
1.F	Implement efficient, agile, and modular approaches to systems development	X	X	X	X	X
1.G	Focus on enterprise application development and interoperability to meet business needs				X	X
1.H	Provide effective, stable, secure, and robust web capabilities and content management	X	X	X	X	X
1.I	Maintain excellence in implementation and compliance with government-wide systems and requirements	X	X	X	X	X
1.J	Provide the virtual office, infrastructure on demand, collaboration, & high capacity storage			X	X	X
1.K	Provide effective business process, workflow, and project & system management solutions	X	X	X	X	X

KEY PERFORMANCE INDICATORS

- All infrastructure services are continuously monitored against published and agreed-upon service level agreements
- Email and network connectivity is 100% available with service levels at or above published service level agreements
- Actual data storage costs are at or below public sector benchmarks
- 80% of all IT systems hosting requirements are met by standard infrastructure service offerings
- Engineering support is available to all prioritized programs/ projects
- Sustained rate of technology upgrade that ranges from 5-15% annually
- Infrastructure design and strategy are aided via external advice
- Application performance and availability meet or exceed published service levels

PROGRESS TO DATE and SUCCESS STORIES

Data Center Modernization to Tier 4

OIM successfully completed the data center modernization and migration project which provided an advanced computing infrastructure that is secure, scalable, flexible and reliable and able to meet the agency's mission. As a result of this initiative, which includes extensive virtualization, the FDA now has a Tier 4 production data center environment with a secure FDA computing environment.

A Tier 4 data center is considered the most robust type of data center and is inherently less prone to failures due to its fully fault-tolerant cooling, power and network links engineered to exceed 99.995% availability (less than 27 minutes of downtime per year). FDA has formalized the development, test, pre-production, and production environments. This provides an internal cloud computing environment which reduces FDA's costs for environment setup and support, and provides agility not previously possible.

Server and Environment Virtualization and Consolidation

Additionally, FDA has established consistency and standardization through new operational procedures and processes. Key outcomes achieved which enhance FDA operational efficiency and cost savings include an 89% server reduction through virtualization and a reduction in the number of Agency systems from 397 to 265. Virtualization allows FDA to run multiple systems on a single high-performance server instead of each system requiring a separate server. Through virtualization FDA has reduced the physical server footprint, which demonstrates savings in power consumption costs from a server and data center standpoint and allows FDA to utilize equipment and support resources far more efficiently. Approximately 110 database servers were consolidated into 18 servers, for an 84% reduction of physical equipment. The overall data center infrastructure reliability has increased from 98.3% to 99.9996%, meaning that unscheduled server downtime has been reduced from 6.6 days per calendar year to approximately 30 seconds. A high-performance computing enclave has also been established to support the FDA's bioinformatics initiatives. FDA's new data centers already meet or exceed all 2012 and 2013 Executive Order and HHS green computing and consolidation goals. Server uptime has been increased, and OIM is committed to evaluating complete end-to-end services to assure maximum customer availability at all points in utilization processes.

GOAL #2

Develop the Knowledge Architecture and Infrastructure that enables smooth FDA operations, efficient review processes, risk-based analytics, and secure and seamless collaboration with public and private partners

DESCRIPTION

The availability and usability of data is essential to the speed and efficiency of decision making at FDA. Some data must be available real-time 24:7 and is required to be translatable from data to information and knowledge almost instantly, as in the cases of imports review and the evaluation of medical adverse events. Other data-driven processes require deeper contemplation and multivariate analysis capability, such as the pre-market review of biopharmaceuticals.

OIM at FDA supports and enables the availability, usability, connectivity, inter-operability, security, analysis and visualization of the vast array of data types and processes that stream into, through and out of FDA on a daily basis. The intent of this goal is to make data available and consumable within and across the FDA and to enable a learning and knowledge network that enables risk-based analytics on a scale that routinely handles global sources and volumes of data. This goal is also intended to drive the global data-sharing, risk analytics, and reliance on third parties that is envisioned in FDA's 2011 special report, Pathway to Global Product Safety and Quality.

OBJECTIVES

2.1 Enable Seamless Data Availability via End-to-End and Standards-Based Master Data Capability by 2015

The FDA must have well-defined processes for the development, adoption, harmonization, and implementation of data standards to enhance interoperability of information acquired from multiple sources, to align its systems to Health IT and other standards, and to interface with industry and other government agencies both at home and abroad.

2.2 Enable Enterprise Data Management by 2015

Enterprise Data Management provides a coordinated and comprehensive approach to ensuring data integrity and that FDA's data and information are accessible and secure.

2.3 Enhance the Efficacy of FDA Programs via Integrative Informatics by 2014

The scientific computing technology and data infrastructure enable advanced analytics, integrative analysis, data aggregation and disambiguation and a wide range of advanced computational needs, while leveraging agency-wide foundational capabilities made of reusable components.

2.4 Establish Efficient and Effective Operational Governance by 2012

FDA and OIM operational and investment strategy governance provides a business-driven, business-oriented investment management framework integrating critical organizational disciplines to successfully improve and ensure cross-agency integration and alignment of IM investments (see the U.S. General Accounting Office (GAO) -defined IT Investment Management Capability Maturity Model).

2.5 Develop and Utilize Enterprise Architecture (EA) as an Enabling and Driving Force by 2013

FDA IM EA provides a business-driven framework that captures the current state, the desired end- state, and develops solutions and transition plans for FDA's business architecture, data architecture, systems architecture, technical architecture, security architecture, and standards via utilization of the GAO-defined IT EA Management Maturity Framework.

2.6 Utilize Rigorous Information Security Practices to Drive Innovation and Collaborative Data Access by 2012

FDA IM provides a secure IM environment with multiple levels of firewall protection, accurate personal identity verification, up-to-date intrusion prevention, detection, and response systems, and effective user security awareness. These essential principles will be the key enablers of technological innovation and worldwide collaboration.

MAJOR ACTIVITIES and TIMING

		FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
2.A	Define, advocate, and implement standards for information exchange consistent with Health IT		X	X	X	X
2.B	Implement harmonized controlled vocabularies through enterprise thesaurus management				X	X
2.C	Implement comprehensive Master Data Management for key FDA data elements			X	X	X
2.D	Utilize standardized enterprise information flow processes with modern data warehousing				X	X
2.E	Transform legacy data to standardized formats for harmonized data warehouses					X
2.F	Coordinate enterprise management and injection of data quality throughout the Data Life Cycle					X
2.G	Utilize structured data modeling and architecture methods to assure data quality and consistency		X	X	X	X
2.H	Provide efficient tools for search, retrieval, reporting, auditing, and utilization of data		X	X	X	X
2.I	Provide for fully electronic submissions and reviews with advanced analytics and tools			X	X	X
2.J	Provide efficient solutions for Comprehensive Product Life Cycle Management				X	X
2.K	Provide advanced document and knowledge management and collaboration environments			X	X	X
2.L	Provide infrastructure for scientific computing, scientific enclaves, and laboratory support	X	X	X	X	X
2.M	Establish shared investment management processes for Agency and OIM leadership		X	X	X	X
2.N	Establish effective IT investment governance processes for operations and implementation		X	X	X	X
2.O	Establish EA framework that integrates business, data, and systems			X	X	X
2.P	Maintain a secure environment where security, privacy, and confidentiality are ensured	X	X	X	X	X
2.Q	Establish processes to identify and evaluate new technologies and innovative approaches	X	X	X	X	X

KEY PERFORMANCE INDICATORS

- There is a collaboratively managed menu of effective analytical tools for all primary data types
- The FDA Security Operations Center monitors and remediates billions of intrusion attempts against FDA IT Systems annually with no major information security breaches
- 80% of systems delivery is based upon pre-designed architectural roadmaps
- Strategic blend between center-specific and enterprise systems development is achieved
- Risk-based analytics drive 10-15% of annual change in inspection prioritization
- Data availability is greatly increased as measured by imports staff
- Knowledge management layers exist in greater than 30% of software applications
- At least one new major component of FDA strategic plan is data-enabled annually

PROGRESS TO DATE and SUCCESS STORIES

Personal Identity Verification Implementation

The Division of Technology assumed a leadership role in the HHS Personal Identity Verification (PIV) compliance effort [Homeland Security Presidential Directive (HSPD) -12] ensuring that FDA personnel had the ability to use PIV cards to access their computers and FDA facilities. PIV cards are an alternative to users having multiple accounts and passwords and are a much safer way to secure sensitive data and systems.

Progress on Automated Risk Management

The Division of Technology completed a comprehensive Automated Risk Management plan in support of Office of Management and Budget (OMB) Directive 10-15 and began the initial phases of implementation. Automated Risk Management is a methodology for real-time risk management of IT systems and data. Introduction of Automated Risk Management at the FDA will greatly streamline the introduction of new IT systems and capabilities and will ensure that proper protections are applied as threats arise and diminish.

Recognition as an HHS-wide Information Security Center of Excellence

The FDA was recognized as an HHS-wide Information Security Center of Excellence in acknowledgement of the Division of Technology's leadership in Personal Identity Verification (HSPD-12), Automated Risk Management (OMB 10-15), and compliance with the Federal Information Security Act of 2002.

Scientific Enclave Delivery

The Division of Technology delivered the Scientific Enclave environment to facilitate scientific computing collaboration within the FDA, across HHS operating divisions, and with Industry and Academia while ensuring that the appropriate controls are in place to protect the sensitive and proprietary data of patients and sponsors. The Scientific Enclave environment is designed for rapid implementation of collaboration environments where communities of scientists can come together to analyze large, integrated data sets and address important questions confronting clinical medicine. This accomplishment has been publically acknowledged by the Secretary of HHS.

Progress on Enterprise Architecture

EA completed a draft functional model to align with the CIO's Plan, Build, Run paradigm. It depicts EA threaded throughout the paradigm; as a result we are now determining the appropriate staffing needs. EA is working on options for the Architecture/ Engineering Review Board which will play a pivotal role in the new governance model being established at the FDA.

Introduction of Six-sigma Process Improvement

EA continues to work with one of the CIO's Senior Technical Advisors on process improvement. The first processes work (using six sigma techniques) is data architecture and management. We have the process flows developed, have met internally, and are starting to socialize the model across the Agency. We are in the preliminary stages of starting the next process which is service architecture. There are three other Green-belt projects underway within OIM.

GOAL #3

Create Fiscal Opportunity via the efficient delivery of high value services that reduce costs and create reinvestment opportunities

DESCRIPTION

Currently, information technology expenditures and overhead account for approximately 12% of the total FDA budget. The amount of value realized for this significant investment must be continuously monitored and optimized. Once the infrastructure has been optimized, by rigorously managing all technology overhead costs, it is estimated that 5-15% of new capability can be delivered annually without any increase in costs. This can be accomplished by the strategic re-investment of a portion of savings realized through cost optimization. Examples of cost savings opportunities are in infrastructure standardization, elimination of redundant infrastructure and computer applications, automation, a strategic balance of insourcing and outsourcing of resources and capabilities and vendor management, with this last opportunity being the largest opportunity by far.

OBJECTIVES

3.1 Develop an improved financial model for IM investment and budgeting at FDA that increases transparency and provides an actionably direct understanding of technology spend at FDA by 2013

Evolve the current and historical allocation-based financial models with a more direct set of approaches that enable the understanding of fixed, variable and opportunity costs.

3.2 Develop a strategic vendor management strategy and capability in cooperation with the FDA contracting office and HHS by 2014

Current approaches to IT contract management and strategy are rate-limited by procurement personnel and based upon outdated technology practices, such as fixed-price approaches for technology delivery. These contracts can be greatly optimized via the application of strategic resources and up-to-date procurement strategies to yield the benefits of tens of millions of dollars saved annually.

3.3 Develop models that transparently connect the actual costs of all major services and the service level agreements for those services by 2014

By clarifying the actual cost of IM and mobility costs by service, customers can make informed choices that increase productivity, enable re-investment and create cost savings.

3.4 Implement effective program management methodology by 2013

By implementing a Program Management Office and HHS-mandated Enterprise Performance Management Life Cycle processes FDA can coordinate systems development and maintenance processes across all components of FDA's information management activities.

MAJOR ACTIVITIES and TIMING

		FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
3.A	Establish integrated portfolio management, Capital Planning and Investment Control (CPIC), and project execution and cost accounting		X	X	X	X
3.B	Provide effective support for IM-related acquisitions through FDA contracting services and modernize procurement strategies		X	X	X	X
3.C	Maintain excellence and transparency in fiduciary accountability and resource management and IM procurement services		X	X	X	X
3.D	Implement standardized IM program management oversight, ensuring evaluation of projects at critical stages in their development			X	X	X

KEY PERFORMANCE INDICATORS

- Measurably closer alignment between actual spend and budget forecasts available transparently throughout the fiscal year
- Significant decrease in unplanned spending in fourth quarter
- Continuous cost optimization on all major services
- 20% overall decrease in spend on major projects via vendor management
- 10% decrease in annual support of commercial software licensing
- Sustained rate of technology upgrade that ranges from 5-15% annually
- Annual decrease in cost of data storage

PROGRESS TO DATE and SUCCESS STORIES

Establishment of the FDA OIM Program Management Office (PMO)

The FDA OIM PMO is the organizational component established by the CIO that defines and maintains the standards of IM program and project management processes within FDA. The PMO strategically addresses areas for process improvement and fills critical gaps in program coordination, collaboration, and program and project management across all FDA information management activities. The PMO strives to standardize and introduce repeatable processes and provide documentation, guidance, processes and metrics in order to achieve successful IM projects that are delivered in scope, on time and within budget constraints.

Field Office Infrastructure Refresh

The FDA has is currently completing its field IT infrastructure modernization supporting 220 FDA field locations including Office of Regulatory Affairs, Center for Drug Evaluation and Research and Center for Food Safety and Applied Nutrition facilities. This effort includes network connectivity and monitoring for all field locations, implementation of Voice-Over-IP phone integration for medium-to-large sites, a streamlined enterprise-standard security patch distribution system, standardized file and print sharing for all field locations, and laboratory instrument backups for 13 field locations.

The number of file and print servers has been reduced through this effort from 110 prior to this effort to 27 today. Consolidation, virtualization and standardization have greatly reduced capital equipment and operations and maintenance costs for field IT infrastructure, achieving a Return on Investment (ROI) of nine months with recurring annual savings of $2.65M.

Lease Buyout of Contractor Hosted Data Center (CHDC) Equipment

Purchase of leased equipment in the FDA's primary production data center in Ashburn, Virginia achieved a large savings and will greatly simplify the data center support contract re-compete process, as both data centers are now Government Furnished Equipment (GFE) rather than a mix of lease and GFE. Overall net savings of $9.1M was achieved.

Success Story: Project and Portfolio Management Tool Implementation

A central electronic tool capable of harnessing project and portfolio management information in a single central repository was implemented by OIM in 2010, with reporting capabilities to mine information that can be accomplished by anyone with access and privileges to these data. This tool is used to centrally manage and communicate project, contract, and investment data under the FDA IT Portfolio. Approximately $0.4M in savings has been realized to date.

Success Story: Contract Management Support

OIM continually reviews IT contracts to look for cost saving opportunities while maintaining or increasing benefits to FDA programs. A key area identified for improvement was Interagency Agreements (IAGs). IAGs can often save both time and money, but since we are paying another agency to perform contract management this is an area we review periodically to re-evaluate cost efficiency. We determined that bringing two of our IAGs 'in house' would provide cost savings and more effective vendor relationships. By partnering with the Office of Acquisitions and Grant Services (OAGS), the majority of Oracle and Microsoft services are now handled internally by FDA, saving over $0.4M in the first year, with an expected savings of over $2M over the next five years.

Success Story: Standard IT Project Support Tools

We have reduced costs around tools that support application development (Configuration Management, Test, Requirements, Issue tracking) by centralizing and standardizing the tools we and our contractors must use. The project teams now have a better knowledge base around these tools, and we can provide expertise to project teams that need support. We reduced total number of tools from 20 to 14, saving $0.25M per year in license and support costs, as well as additional cost avoidance through standardization.

GOAL #4

Develop a leadership pipeline of highly engaged, qualified and customer-centric employees that are experts in technologies and in the business and scientific domains which they serve

DESCRIPTION

While the FDA information technology budget represents approximately 12% of the total FDA budget, the federal OIM staff accounts for less than 4% of the FDA workforce. Even when the average amount of supplemental contractors is added, the total OIM workforce is less than 7%. As these resources are precious and can be rate-limiting, it is essential that FDA OIM staff be intentionally developed, carefully enhanced when growth is possible, and managed diligently. This is especially true given the rapid rate of change of technology, analytics and IT service models. The staff must be engaged, lean, active learners, agile and efficient if FDA is to meet its essential mission.

OBJECTIVES

4.1 OIM staff must be transformed into a proactive transformational entity that enhances relationship-building among its stakeholders while improving the integration of business, strategy, performance, and technology by 2014.

Information Management is an essential driving and operational force for the mission of the agency and as that mission evolves technologically, scientifically and legislatively, so must the OIM staff. The FDA and OIM leadership are committed to an intensive approach to modernizing the OIM workforce.

4.2 OIM is results-driven, providing value to its stakeholders through proactive, innovative, and strategic thinking, customer service, performance management, and governance of IM business solutions by 2013

As important as Information Management is to the FDA mission, the OIM staff does not generally, participate directly in the regulatory work of the Agency, e.g., pre and post market evaluation of drugs and devices, inspections, etc. OIM exists to serve the FDA employees that do perform the core mission functions at FDA and it is this service that is the sole basis of OIM progress.

4.3 The FDA and OIM information management team must have strong visionary leadership that sustains the training and resources needed to support the Agency Mission, and that establishes a culture of learning, excellence, transparency, and accountability by 2012

OIM leadership must be strong, collaborative, rigorous, engaged and transparent in the performance of their duties and in the management of all OIM staff.

MAJOR ACTIVITIES and TIMING

		FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
4.A	Implement strategic workforce planning and an IM human capital management plan, with tactical plans for managing the IM workload		X	X	X	X
4.B	Implement individual training, skill development, and professional development and career management programs for IM staff	X	X	X	X	X
4.C	Implement active recruitment, hiring, and retention processes that are built upon a skills inventory, needs assessment, and gap analysis		X	X	X	X
4.D	Provide continuous interactive support and communication for FDA information systems users and stakeholders		X	X	X	X
4.E	Provide efficient Helpdesk, technical support, and other customer support & training services	X	X	X	X	X
4.F	Maintain a culture of excellence, learning, and continual business process improvement, including strategic planning, continuous program evaluation, and quality management systems			X	X	X

KEY PERFORMANCE INDICATORS

- 80% of all VIP and senior support staff are Microsoft Certified
- 75% of all Oracle Database Administrators (DBAs) are Certified
- OIM technology staff skillset distribution meets or exceeds proportions recommended by external benchmarks
- All OIM employees have at least one significant technology or customer service domain goal in their Performance Management Appraisal Program (PMAP) critical elements
- All OIM people managers have one significant PMAP goal on staff development
- OIM self-funds an annual staff training plan that ensures at least one-half of staff are upgrading at least one critical skill or capability
- Perform an annual skills assessment across OIM with input from across FDA

PROGRESS TO DATE and SUCCESS STORIES

CIO Role Expansion and Recruitment

In late 2011, the FDA leadership developed an expanded role definition that added to the Chief Information Officer a second title of Chief Scientist Informatics. This expansion allowed the recruitment of a senior IT and scientific leader that would not only focus on technology but that also had the medical, scientific and analytic knowledge to truly drive the FDA mission forward.

OIM Organizational Stabilization

As of September 2011, four out of seven OIM senior leadership roles were occupied by employees with 'acting' status. Several of the roles had gone without permanent leaders for more than 3 years. As of June 2012, three of the four roles have been filled with permanent leaders, including the CIO and Deputy CIO, and there is an offer extended on the fourth.

OIM Staff Training Funded and Ongoing via Reduction of Consulting Fees

During the fiscal years 2010-2011, the OIM training budget had been eliminated as cost savings. In early FY 2012, this budget was re-established via the elimination of consulting fees. The result is that active training programs are ongoing in all FDA OIM divisions.

Project Management Training

The FDA Project Management (PM) Certification Program over the past five years has clearly demonstrated that "leadership is action, not position." The goal of the PM Certification Program is to educate project managers in the discipline of good project management as defined by the Project Management Institute and Project Management Body of Knowledge. During these past five years there have been approximately 238 government and Commissioned Corps FDA (OIM and non-OIM) employees who have graduated from the program achieving a Masters Certificate in Project Management. An additional 42 staff graduated this past July.

DRIVERS & FRAMEWORK for the STRATEGIC PLAN

FDA and OIM are responsible for providing the IM infrastructure and services to support FDA's mission to advance the health of the public. It is required to do this according to the following laws and directives, which govern the federal government IM line of business:

- **Federal Records Act of 1950 & National Archives and Records Administration Act of 1984 –** provides framework for records management in federal Agencies; NARA guides in appraising records, regulating and approving disposition, operating Federal Records Centers, and preserving permanent records

- **Privacy Act of 1974 –** balance between government rights to maintain information on individuals and individual rights to have privacy protected – collection limitation, disclosure, secondary usage, record correction, security

- **Competition in Contracting Act of 1984 –** requires, with limited exceptions, that contracting officers promote and provide for full and open competition in soliciting offers and awarding federal government contracts

- **Computer Security Act of 1987 –** establishes minimum acceptable security practices for federal systems; requires creation of computer security plans and training of system users or owners where the systems house sensitive information

- **Government Performance and Results Act of 1993 –** requires agencies to engage in project management tasks such as setting goals, measuring results, and reporting their progress; agencies must produce strategic plans, performance plans, and conduct gap analysis of projects

- **Paperwork Reduction Act of 1980, amended 1995 –** federal agency policies, principles, standards, and guidelines on privacy, confidentiality, security, disclosure, and information sharing; requires OMB approval for information collected from the public; no persons required to respond without OMB control number

- **5 Code of Federal Regulations (CFR) 1320 –** OMB's final rule on controlling paperwork burden

- **Information Technology Management Reform Act of 1996 (Clinger-Cohen Act) –** comprehensive approach for executive agencies to improve the acquisition and management of their information resources – information resource planning; capital planning and investment control process linked to budget formulation and execution; develop, maintain, and facilitate implementation of top-level enterprise architecture

- **Freedom of Information Act of 1996 –** agencies shall make available for public inspection and copying a general index of records and copies of all records, with certain exceptions to protect proprietary and privacy information

- **Health Insurance Portability and Accountability Act of 1996 –** to simplify administration of health insurance; to combat waste, fraud, and abuse; to create national standards to protect medical records; requires adoption of national standards for electronic health care transactions and national identifiers for providers, health plans, and employers; establishes standards for privacy and security of health information, as well as standards for electronic data interchange of health information

- **Government Paperwork Elimination Act of 1998 –** requires that, when practicable, Federal agencies use electronic forms, electronic filing, and electronic signatures to conduct official business with the public; focuses on records management issues; guidance to agencies on securing information in interconnected electronic networks; significantly increased security for government systems

- **Presidential Decision Directive 63 –** Critical Infrastructure Protection (1998) – established Information and Communications as a critical infrastructure segment

- **OMB Circular A-130 –** Management of Federal Information Resources (2000) – policy for the management of federal information resources; integrated life cycle IM planning with budgeting, acquisition, and use of information technology; records management and archival functions; training; protection and safeguards; provide information to the public; limit collection of individually-identifiable information; Capital Planning and Investment Control; Enterprise Architecture…

- **President's Management Agenda (2002) –** technology agenda brings collaboration, participation, and transparency to government in a big way – disclosure management; data sharing; data quality; multichannel information, interaction, and service delivery; data analysis; disruption; and defining and measuring impact

- **Electronic Government Act of 2002 –** using information technology to transform agency business into a more user friendly process; protects confidentiality of data across government and allows key statistical agencies to share business data

- **Federal Information Security Management Act of 2002 –** [Title III of eGov Act] defines a comprehensive framework to protect government information, operations, and assets against natural or man-made threats; agency annual reviews of information security – categorize information, baseline controls, risk assessment, document controls in system security plan, implement security controls, assess effectiveness, determine agency-level risk, authorize information systems, monitor security controls

- **E-Government Strategy (2002) –** implements the President's Management Agenda for e-Government; simplified delivery of services to citizens

- **The National Strategy to Secure Cyberspace (2003) –** national strategy to prevent cyber attacks against America's critical infrastructures; reduce national vulnerability to cyber attacks; and minimize damage and recovery time from cyber attacks that do occur.

- **OMB Circular A-11, part 7 –** Capital Asset Management (2003) – federal budget process and capital asset management processes, Exhibit 300, Enterprise Architecture

- **OMB Circular A-76 –** Performance of Commercial Activities (2003) – requires competition for needed commercial services

- **Homeland Security Presidential Directive 7 (HSPD-7, 2003) –** identify and prioritize critical infrastructure and to protect them from terrorist attacks

- **Homeland Security Presidential Directive 12 (HSPD-12, 2004) –** a mandatory, Government-wide standard for secure and reliable forms of identification issued by the Federal Government to its employees and contractors

- **Federal Acquisition Regulation (FAR, 2005) –** detailed contracting requirements

- **OMB M-08-05 & M-09-32 –** Trusted Internet Connections (2007, 2009) – optimizing of federal individual external internet connections

- **OMB Circular A-127 –** Financial Management Systems (2009) – policies for financial management systems; requires FSIO Certified Commercial (COTS) Systems

- **OMB Circular A-16 –** Coordination of Geographic Information and Related Spatial Data Activities (2010) – coordination and use of geospatial data

- **OMB Directive M-10-15 –** Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management (2010)

- **Telework Enhancement Act of 2010** – Mandates that federal agencies establish policy under which eligible employees may be authorized to telework

- **Executive Order 13589 –** Promoting Efficient Spending (2011)

- **DIGITAL GOVERNMENT: Building a 21st Century Platform to Better Serve the American People –** Information-Centric, Shared Platform, Customer-Centric, Security and Privacy (2012)

- **NIST Security Guidances –** National Institute of Standards and Technology mandates for IT security matters

- **Federal CIO Strategic Plan and 25-Point Reform Implementation Plan**

- **HHS Strategic Plan and Secretary's Priorities**

- **HHS CIO Strategic Plan and Policy/Directives**

- **Office of the National Coordinator for Health IT Directions** relating to Electronic Health Record (EHR) Standards, Federal Health Architecture, Nationwide Health Information Network, EHR Meaningful Use, etc.

- **PCAST Report on Health Information Technology** (2010)

- **PCAST Report on Designing a Digital Future** (2010)

- **Topics with CIO responsibility / oversight (GAO-04-823, GAO-11-634, OMB m-11-29)**

FDA Information Management, generally through OIM, is responsible to Guide Business Needs within Regulations and Mandates – OIM assists the FDA Programs in implementation of their business needs in a way that is acceptable within the boundaries defined by Laws, Regulations, Standards, and other mandates.

Comments or suggestions, please contact either the FDA CIO at FDACIO@FDA.HHS.GOV or John W. Gardner, MD, DrPH at john.gardner@fda.hhs.gov.

ACRONYM LIST

CHDC – Contractor Hosted Data Center
CIO – FDA's Chief Information Officer
CPIC – Capital Planning and Investment Control
DBA – Database Administrator
EA – Enterprise Architecture
FDA – Food and Drug Administration
GAO – Government Accountability Office
GFE – Government Furnished Equipment
HHS – Health and Human Services
HSPD – Homeland Security Presidential Directive
IAG – Interagency Agreement
IM – Information Management
IT – Information Technology
OAGS – FDA's Office of Acquisitions and Grant Services
OIM – FDA's Office of Information Management
OMB – Office of Management and Budget
PIV – HHS Personal Identity Verification
PM – Project Management
PMAP – FDA's Performance Management Appraisal Program
PMO – FDA's OIM Program Management Office
ROI – Return on Investment
Voice-Over-IP – Voice Over Internet Protocol